K122382

OCT 22 2012

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the DYNASTY® BIOFOAM® Shell.

Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd, Arlington TN, 38002 (800) 238-7188
Date:	July 25, 2012
Contact Person:	Dean Nachtrab *Regulatory Affairs Specialist*
Proprietary Name:	DYNASTY® BIOFOAM® Shell
Common Name:	Acetabular Cup
Classification Name and Reference:	888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Class II 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis Class II
Subject Product Code and Panel Code:	Orthopedics/87/ LZO, MBL, JDI
Predicate Devices:	DYNASTY® Acetabular System 510(k)s: K082924

DEVICE INFORMATION

A. Intended Use

The DYNASTY® BIOFOAM® Shells are intended for use in cementless total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients.

Indications for Use

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

B. Device Description

Design features of the shells are summarized below:

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- Shells manufactured from Titanium alloy substrate, coated with BIOFOAM® coating manufactured from commercially pure (CP) titanium
- Solid shell sizes: 46mm-68mm outer diameter
- Three different hole patterns:
  - 10-hole shell sizes: 46mm-76mm outer diameter
  - 3-hole shell sizes: 46mm-68mm outer diameter
  - 5-hole shell sizes: 46mm-50mm outer diameter

The subject DYNASTY® BIOFOAM® Shells were cleared in K121544 for use with metal/metal bearings. The shells are identical to shells in K082924, except that the subject device posses different screw hole patterns. Additionally, the DYNASTY® BIOFOAM® Shells were evaluated via post-impaction analysis of clearance, form and frictional torque. A review of these results concludes that the DYNASTY® BIOFOAM® Shells were cleared in K121544 and are equivalent to predicate devices.

C. Substantial Equivalence Information

The indications for use of the subject DYNASTY® BIOFOAM® Shells, cleared in K121544 for use with metal/metal bearings, are identical to shells in K082924. The design features and materials of the subject devices are substantially equivalent to those shells cleared under K082924. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the subject DYNASTY® BIOFOAM® Shells are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 2 2012

Wright Medical Technology, Incorporated
% Mr. Dean Nachtrab
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K122382
Trade Name: DYNASTY® BIOFOAM® Shell
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: II
Product Code: MBL, LZO, JDI
Dated: September 24, 2012
Received: September 24, 2012

Dear Mr. Nachtrab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122382

Device Name: DYNASTY® BIOFOAM® Shell

Indications For Use:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed.

The DYNASTY® BIOFOAM® Shell is intended for cementless hip arthroplasty.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122382